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| 10/616,278 | 07/09/2003 | Frank Daniel Long | 1341-2 | 2088 |

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HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

| EXAMINER | |
|---|---|
| KRISHNAN, GANAPATHY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/616,278 | LONG ET AL. | |
| | Examiner | Art Unit | |
| | Ganapathy Krishnan | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28, 47-50, 59, 60 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 through 28, which depend from base claim 20, recite hyaluronic acid compositions with specific percentages of hyaluronic acid. Since claim 20 recites two hyaluronic acid compositions it is not clear which of these two the applicant intends to contain the specific percentages recited. For the purpose of prosecution the percentage recited is interpreted to be that of either composition.

Claim 43 recites hyaluronic acid component. It is not clear what this recitation means. For the purpose of prosecution it interpreted to mean a structural feature of hyaluronic acid or hyaluronic acid itself present in the composition, in these and any other claims the term is recited.

Claims 47 through 50 recite hyaluronic acid component comprises hyaluronic acid. It is not clear what this recitation means. For the purpose of prosecution it interpreted to mean a structural feature of hyaluronic acid or hyaluronic acid itself present in the composition, in these and any other claims the term is recited.

In claims 51, 60 and 64 it is not clear what "a lubricant or moisturizing agent in cosmetic or eye drops" means. For the purpose of prosecution it is interpreted to mean a composition consisting of any of the types recited in the claims.

Claims 59 and 60 recite the limitation "composition" in claim 52. There is insufficient antecedent basis for this limitation in the claim. Claim 52 is drawn to a method of treating a condition. For the purpose of prosecution claims 59 and 60 are interpreted as composition claims and not as method claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 43-46, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs (US 4141973).

Balazs teaches in stage V of his isolation process (col. 13, line30-33) ultrapure hyaluronic acid (100% dried powder). This constitutes the hyaluronic acid isolate as claimed in instant claims 1-11. Balazs teaches hyaluronic acid solution (col. 15, lines 62-66; col. 16, lines 63-66). This constitutes the compositions of claims 43-46. Balazs teaches a package containing the ultrapure hyaluronic acid in a physiological buffer solution containing sodium chloride and sodium phosphate (col. 13, lines 33-39). This constitutes a method of producing a product comprising extracting hyaluronic acid composition and incorporating it into the said product and

also purifying the hyaluronic acid prior to incorporation, as claimed in claims 61 and 62. Since the hyaluronic acid of Balazs is ultrapure and is used for therapeutic purposes (col. 13-col. 14) it is both pharmaceutical and cosmetic grade. The source of the said hyaluronic acid is not given patentable weight.

Claims 12-16, 50, 51, 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson et al (US 6255295)

Henderson teaches a composition comprising hyaluronic acid further comprising glucosamine (hexosamine). Henderson gives a wide range for the amount of glucosamine and hyaluronic acid in the composition (col. 24, example 41 through col. 26, example 48). Glucosamine is also preferred as a salt form, one of which is N-acetylglucosamine (col. 11, lines 31-34). Henderson teaches compositions for oral administration (col. 14, lines 40-59). These disclosures of Henderson meet the limitations of claims 12-16, 50, 51, 59 and 60.

Claims 20-28 and 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Osuoji (Biochimica et Biophysica Acta, 1971, 244, 481-483).

Osuoji teaches extraction of hyaluronic acid from membranes obtained from shell-free eggs (membrane separated from egg shell, see page 481, summary and second full paragraph). Osuoji also teaches the purification by precipitation and treatment with ion exchange resin. The hyaluronic acid obtained after this treatment is considered to be substantially pure. This constitutes the methods of instant claims 20-28. The instant claims are drawn to a method for producing hyaluronic acid composition comprising extracting a hyaluronic acid composition. The percentage of hyaluronic acid present in the source is not accorded patentable weight.

Osuoji also discloses the percentage of glucosamine and glucuronic acid (hexose) in the composition (page 482, second paragraph, lines 18-22) and the presence of chondroitin-4-sulphate (see summary, page 481). This meets the limitations of claims 35-39.

Claims 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bracke et al (US 4517295).

Bracke teaches the extraction of hyaluronic acid from a fermentation mixture via diafiltration and treatment with alcohol (col. 2, line 45 through col. 4, line 15). The average molecular weight of the hyaluronic acid obtained is 55,000 (col. 4, lines 64-66). This disclosure is seen to meet the limitations of claims 29-31. The source of the hyaluronic acid is not given patentable weight.

Claims 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakurai et al (US 4716224).

Sakurai et al teach the crosslinking of hyaluronic acid (col. 6, example 2). The crosslinked hyaluronic acid is shown to have a high molecular weight as compared with the starting hyaluronic acid (col. 5, lines 34-36). This disclosure of Sakurai et al is seen to meet the limitations of claims 32-24.

Claims 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson et al (US 6255295)

Henderson teaches a composition comprising hyaluronic acid further comprising glucosamine (hexosamine). Henderson gives a wide range for the amount of glucosamine and hyaluronic acid in the composition (col. 24, example 41 through col. 26, example 48). Glucosamine is also preferred as a salt form, one of which is N-acetylglucosamine (col. 11, lines

31-34). Henderson teaches compositions for oral administration (col. 14, lines 40-59). The compositions of his invention are administered to promote tissue repair and the treatment of arthritic conditions (col. 13 lines 18-21). This meets the limitations of method claims 52-58.

***Joint Inventors***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-19 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson (US 6255295).

Claims 17-19 are drawn to a hyaluronic acid isolate wherein chondroitin sulfate is present in the range 0.05 to 10 wt%. Claims 47-49 are drawn to a composition wherein hyaluronic acid is present in about 1-5 wt%, 80 wt% and 90 wt% respectively.

Henderson teaches a composition comprising hyaluronic acid further comprising glucosamine (hexosamine). He also teaches a composition comprising chondroitin sulfate and glucosamine. The weight range for all the three components in his composition is broad and covers the percentages instantly claimed (see col. 18, examples 14-16 and col. 24, examples 41-43). Both these compositions have been taught to be useful for promoting tissue repair, and treatment of arthritis individually (col. 13, lines 18-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Henderson to make a composition comprising hyaluronic acid and chondroitin sulfate since both are seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to make a composition comprising hyaluronic acid and chondroitin sulfate since both are individually taught for the treatment of tissue repair and treatment of arthritis and hence it is logical to combine the two and also to adjust the percentage of the chondroitin sulfate as instantly claimed in order to make a composition with the optimal concentration of chondroitin sulfate.

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osuoji (Biochimica et Biophysica Acta, 1971, 244, 481-483) in combination with Baker et al (Biochemical Journal, 1962, 82, 352-361).

Osuoji teaches extraction of hyaluronic acid from membranes obtained from shell-free eggs (membrane separated from egg shell, see page 481, summary and second full paragraph). Osuoji also teaches the purification by precipitation and treatment with ion exchange resin. The hyaluronic acid obtained after this treatment is considered to be substantially pure. This constitutes a method of producing hyaluronic acid. However, Osuoji does not specifically disclose the isolation of chondroitin sulfate.

Baker et al disclose the presence and extraction of chondroitin sulfate (page 356, right column, lines 10-31). The chondroitin sulfates also comprise 35% of the total polysaccharides (page 360, right column, summary #4) in addition to the presence of hexosamine (page 356, middle of right column).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Osuoji and Baker in a method to extract hyaluronic acid from a composition wherein another naturally occurring substance like chondroitin sulfate is also present, with a reasonable amount of success since the presence of both in the same composition and the method of extraction of both are taught in the prior art.

The idea flows logically from the fact that the combination of the teachings would give a method of obtaining a composition comprising both hyaluronic acid and chondroitin sulfate from the same source.

Claims 61, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs (US 4141973) in combination with Henderson et al (US 6255295).

Claims 61, 63 and 64 are drawn to a method for producing a product comprising extracting a hyaluronic acid composition and incorporating it in the said product; wherein the said hyaluronic acid composition comprises hyaluronic acid and at least one other constituent selected from a hexosamine, chondroitin sulfate and combinations thereof and wherein the said product is selected from the group consisting of a lubricant, moisturizing agent, eye drops, orally administered nutraceutical or locally administered composition.

Balazs teaches a method of extracting hyaluronic acid composition and incorporating it in a package containing the ultrapure hyaluronic acid in a physiological buffer solution containing sodium chloride and sodium phosphate (col. 13, lines 33-39). This constitutes the method of producing a product comprising extracting a hyaluronic acid composition and incorporating it in the said product. However, Balazs does not teach a method wherein the composition comprises hyaluronic acid and one other constituent selected from the group consisting of a hexosamine and chondroitin sulfate and wherein the said product is selected from the group consisting of a lubricant, moisturizing agent, eye drops, orally administered nutraceutical or locally administered composition.

Henderson teaches a composition comprising hyaluronic acid further comprising glucosamine (hexosamine). He also teaches a composition comprising chondroitin sulfate and glucosamine (see col. 18, examples 14-16 and col. 24, examples 41-43). The compositions of his invention can be in oral dosage forms like capsules or tablets (col. 14, lines 40-59). However,

Henderson et al does not teach a method for producing a product comprising extracting a hyaluronic acid composition and incorporating it in the said product.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Henderson and Balazs in a method for producing a product comprising extracting a hyaluronic acid composition and incorporating it in a product which comprises at least one other constituent and the type of product as instantly claimed since both are seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to do so since according to Balazs hyaluronic acid is obtained from natural sources by extraction and there is a large body of literature all of which deal with methods of extracting the hyaluronic acid from these sources (col. 1, lines 59-63). Henderson teaches compositions comprising hyaluronic acid, chondroitin sulfate and glucosamine that have several beneficial effects including treatment of arthritis and promotion of tissue repair (col. 13, lines 18-35). Hence it would be logical to use the art tested extractive methods for obtaining hyaluronic acid and combine it with a hexosamine like glucosamine and chondroitin sulfate to make compositions and nutraceutical.

***Conclusion***

1. Claims 1-64 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600